RTI

IRB ID Number 12808

Office of Research Protection
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: Comparing the Effectiveness of Traditional Evidence-Based Tobacco Cessation Interventions to Newer and Innovative Interventions Used by Comprehensive Cancer Control Programs
RTI Project Number: 0211965.014 **RTI Proposal Number** (if no Project Number)
Project Leader: Jennifer Duke
Project Team Member Contact (if different from Project Leader): Nikie Sarris
Source of Funding for this Study: CDC
Date Submitted to IRB: February 10, 2011
Level of Review *(check one)*:
Full ☐, IRB Meeting Date:
Expedited ☒, category: 7: Behavioral - surveys, focus groups, etc.

Type of Review *(check one)*:
- ☐ Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)
- ☐ Pretest/Pilot Test:
- ☒ Full Implementation
- ☐ Amendment, describe:
- ☐ Add study site(s):
- ☐ Renewal
- ☐ Study Closure

IRB Approval of Special Conditions *(check all that apply)*:
- ☒ Waiver of Signed Informed Consent/Parental Permission
- ☐ Participation of Pregnant Women (**Worksheet B** submitted by project team)
- ☐ Participation of Prisoners (**Worksheet C** submitted by project team
- ☐ Participation of Prisoners in DHHS-funded studies (OHRP acknowledgement received)
- ☐ Participation of Minors (**Worksheet D** submitted by project team)
- ☐ IRB Agreement of Nonsignificant Risk Device Study Determination

Please note the following requirements:
- If **unexpected problems** or **adverse events** occur, the project team must notify the IRB.
- If there are **changes** in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: **February 17, 2012**
(No human subjects research can occur after this date without continuing review and approval.)

Signature - IRB Member or Chair

February 17, 2011
Date of IRB Approval

David Borasky
Name - IRB Member or Chair (print or type)

☒ Copy sent to project leader on: February 17, 2011
☐ Entered into MIS

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RESEARCH TRIANGLE INSTITUTE
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
Request for Exemption from IRB Review

To request approval for exemption from Institutional Review Board (IRB) review, the Project Manager (includes Project Director or Leader, Principal Investigator, or Survey Manager) must complete this form and deliver the request to an IRB Administrator. The Project Manager will be notified if more information is necessary and the results of the determination.

Date: February 10, 2011 **RTI Project/Proposal No.:** 0211965.014
(IRB ID for this project is 12808)

Project Title: Comparing the Effectiveness of Traditional Evidence-Based Tobacco Cessation Interventions to Newer and Innovative Interventions Used by Comprehensive Cancer Control Programs

Project Manager: Nikie Sarris **Sponsor:** CDC

Date Participation of Human Subjects Scheduled to Begin:

A. Brief Description of Study Procedures and Participant Population:
In the summer of 2010, the CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCD) awarded RTI a contract to evaluate the effect of traditional versus innovative strategies to promote cessation interventions (i.e. state Quitlines) and increase cessation rates. This IRB application is focused on one of the three study components: *The Promotional Activities Study.*

The purpose of the 'Promotional Activities Study' is to assess the comparative effectiveness of traditional promotion methods (e.g. television; radio; print advertising) versus newer, innovative promotion and educational methods (e.g. cessation Web sites; web banner ads; social media platforms; mobile applications) in increasing calls to state Quitlines among targeted populations. During a 24 month study period, RTI will monitor, describe, and report on ongoing activities from up to 50 participating states to promote the Quitlines.

The 'Promotional Activities Study' will attempt to address the following study aims:
1) To better understand the types of innovative promotional activities states implement, by summarizing media buys and conducting a content analysis of messaging strategies utilized.2) To describe the reach and utilization of innovative promotional and educational activities (e.g. states' cessation Web sites, social media platforms, and mobile applications).
3) To compare audiences reached via innovative activities with those reached via traditional promotional activities in terms of number and demographic profiles

The sample size will ultimately be determined by how many states agree to participate in the study (i.e. up to 50 states). Participating states will provide RTI with media buy information related to all cessation promotional activities, as well as permission to extract Quitline call volume data from the National Quitline Data Warehouse. If available, RTI will also attempt to obtain web traffic data via a web analytic platform, such as Google Analytics.

Typically, only 1-5% of smokers call their state Quitline in a given year. Quitline call volume rates are positively associated with the level of advertising promoting the Quitline. Therefore, the overall sample size will also be determined by the level of promotional activities, the smoking prevalence, and the utilization rate of cessation activities in each participating state.

B. Description of Physical, Psychological, Social or Legal Risks to Participants:
This is an observational, records extraction study; therefore, there are minimal risks associated with this study. Aggregate data or de-identified data only will be extracted to conduct this study. There are no other procedures in place to reduce or alleviate risks.

C1. For educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview research with adults:

1. Is information recorded in such a manner that human subjects can be identified, directly *or through identifiers linked to the subjects?*

[ ] Yes [ ] No [X] NA

If yes, explain:_____

2. Would any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing employability or reputation?

[ ] Yes [ ] No [X] NA

If yes, explain:_____

C2. For research with existing data, documents, records, pathological or diagnostic specimens:

1. Are the sources of the data publicly available?

[ ] Yes [X] No [ ] NA

If no, explain: Aggregated data relating to Quitline call volume are available through state Quitline vendors and the National Quitline Data Warehouse. Website traffic data will be obtained using GoogleAnalytics and other free public programs (e.g. Facebook, Twitter). Data will be purchased from comScore, Inc. to measure how many adults viewed state online ads and whether exposure to these ads were associated with visits to the state cessation Web sites or other cessation-related online searching behavior.

2. Is information recorded in such a manner that human subjects can be identified, directly *or through identifiers linked to the subjects?*

[ ] Yes [X] No [ ] NA

If yes, explain:_____

D. Describe other categories of exempt research[1] here:

[1] Note: Categories C1 and C2 above are the most common types of research conducted at RTI that may be exempt from IRB review. For a complete list of exemption criteria, please see below.

----------Space below this line for IRB use only.----------

Decision of IRB Coordinator or Chair

Name of IRB Coordinator or Chair making exemption determination: David Borasky

Please check appropriate answer(s):

I agree that this study is exempt [45CFR46.101(b)] from IRB review based upon the information provided by the Project Manager above. (Check applicable category below.)

__(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

__(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

__(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

_X_(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

__5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

__(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Signature of IRB Coordinator or Chair named above

February 14, 2011
Date

Version 11-30-00